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K022231
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510 (k) Summary

Device Name:
Normed Distal Radius Reconstruction System

Device Identification:
Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Class II

Product Code:
87 HRS (21 CFR – 888.3030)

Normed Distal Radius Reconstruction System consists of a series of titanium plates in various shape and length in left and right curved configurations, which are attached to the bone using 2.7 mm diameter titanium bone screws. The plates are available in 8, 11, and 13 holes with 2.0 mm plate thickness and can be contoured as needed to fit the specific anatomy. The self-tapping 2.7 mm screw diameters will be available in hex-lock screw head designs, in sixteen length 8 through 38 mm long in 2mm intervals. A hand fixation table system is also available for the surgeon to rest the injured hand during the surgery.

Normed Distal Radius Reconstruction System intended for use in internal fixation of small bones – primary the distal radius in the forearm such as, compression fractures, intra-articular fractures, displaced fractures and surgical reductions.

Official Contact Person:
Albert Enayati
President
Osteomedics Inc.
809 Carter Lane
Paramus, NJ 07652
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E-mail: osteomedics@aol.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 13 2002

Osteomedics, Inc.
Albert Enayati
President
809 Carter Lane
Paramus, New Jersey 07652

Re: K022231
Trade/Device Name: Normed Distal Radius Reconstruction System
Regulation Number: 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: July 8, 2002
Received: July10, 2002

Dear Mr. Enayati:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for use

510 (k) Number (if known): K022231

Device Name: Normed Distal Radius Reconstruction System.

Indications for use:

Normed Distal Radius Reconstruction System intended for use in internal fixation of small bones – primary the distal radius in the forearm such as, compression fractures, intra-articular fractures, displaced fractures and surgical reductions.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription use_____ OR OVER – THE – COUNTER USE_____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022231